



जैव प्रौद्योगिकी विभाग
Department of Biotechnology
Ministry of Science & Technology
Government of India



EUROPEAN UNION

ANNOUNCEMENT INDIA-EU COOPERATION ON RESEARCH & INNOVATION (R&I)

DBT ANNOUNCES CO-FUNDING PARTNERSHIP UNDER THE EU FRAMEWORK PROGRAMME ON R&I 'HORIZON EUROPE' CALLS 2023-2024

Collaboration in Science, Technology and Innovation (STI) plays an increasingly important role in the EU-India Strategic Partnership. In line with the EU-India Strategic Partnership: A Roadmap to 2025, and the Joint Science and Technology Steering Committee meeting on 12 February 2021, the Department of Biotechnology (DBT), has identified calls for proposals in the Work programmes 2023-2024 of the EU R&I Research and Innovation Programme 'Horizon Europe', which it considers of mutual interest and aiming at jointly tackling global challenges.

For this, DBT has established a mechanism outlining the conditions upon which it will co-fund the successful Indian entity/ies and in which call topics (hereafter Co-Funding Mechanism or CFM).

The CFM will apply to the call topics earmarked by DBT in areas of **pandemic preparedness and response, brain disorders, biofuels and healthy & environmentally-friendly food**. This notice explains in the different Sections hereunder how to prepare and submit a co-funded project.

In **Section 1** the **five call topics** earmarked by DBT for co-funding are listed. The list indicates the exact Call IDs, the opening and closing date of the call, the type of action provided and the link to the full call text as published in the Horizon Europe Funding & Tenders Portal.

In **Sections 2 and 3**, the various modalities of participation that the Indian applicants have to comply with, including the Administrative and Financial Considerations (see Annex 1) is outlined.

All proposals have to be submitted to **both** the Horizon Europe Funding & Tenders Portal and to DBT. The EU will only evaluate the proposal submitted to its portal. DBT expects to receive the same copy with in addition all details on the budget the Indian entity requires for its participation. Budget information to be provided in prescribed format and in Indian Rupees. In the absence of this, DBT will disqualify the Indian participants from funding (see **Section 4** hereunder).

At the end of the notice, information is provided on how to access and go about

'Horizon Europe' formalities, which also Indian applicants have to comply with (Annex 2) and on how to find partners (Annex 3).

For the complete call text click [Horizon Europe Funding & Tenders Portal](#) including the general conditions and modalities, and in particular the specific call conditions on the given call topic. Please read carefully the call text itself, which is the only legally binding text.

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SECTION 1: LIST OF CO-FUNDED CALL TOPICS

The CFM applies only to the call topics in HE Work Programme 2023-2024 listed hereunder:

S. NO.	Title	Topic Identifier	Type of Action	Opening Date	Closing Deadline
HEALTH					
1.	Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential	HORIZON-HLTH-2023-DISEASE-03-04	RIA	12 Jan 2023	13 Apr 2023
<p>Proposals should address all of the following areas:</p> <ul style="list-style-type: none"> • Preclinical work and proof-of-concept/first-in-human studies and early safety and efficacy trials for testing new or improved anti-viral therapeutics, with a clear regulatory and clinical pathway. Phase IIb/III phase trials will not be supported. • Innovative delivery systems and suitable safety profiles for broad use should be considered when possible. Attention should be paid to critical social factors such as sex, gender, age, socio-economic factors, ethnicity/migration, and disability. • Application of novel approaches and widely applicable workflows (e.g. artificial intelligence) for rapid and reliable identification of broad-spectrum anti-viraltherapeutics. Read More 					
2.	Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders	HORIZON-HLTH-2024-DISEASE-03-13-two-stage	RIA	30 Mar 2023	19 Sep 2023 (First Stage), 11 Apr 2024 (Second Stage)
<p>Proposals should address all of the following aspects:</p> <ul style="list-style-type: none"> • Proposals should aim to validate biomarkers that can reliably confirm early stages of the human brain disorder and guide treatment/ intervention selection. • Proposals should aim to provide evidence supporting the regulatory acceptance of the biomarkers. • Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new key data. • Inclusion of patients or patient organisations in the research is strongly encouraged, as to ensure that their views are considered. • Sex and gender aspects, age, socio-economic, lifestyle and behavioural factors should be taken into consideration in the study. • To enable sharing of samples, quality data and advanced analytical and digital tools, consideration should be made for using infrastructures already developed at the European or national level. • To enable the management of brain disorders, consideration should be made in demonstrating the gained cost efficiency. Read More 					
3.	Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential	HORIZON-HLTH-2024-DISEASE-08-20	RIA	26 Oct 2023	11 Apr 2024
<p>Proposals should address several of the following areas:</p> <ul style="list-style-type: none"> • Identification and characterisation of receptors on the host cell that enable the docking and internalisation of a virus with a particular emphasis on the diversity of cellular entry receptors and tissue specificity. 					

- Identification and characterisation of viral surface proteins that are capable of interacting with host target cells.
- Characterisation of the mechanism of viral uptake in the host cell with regard to the topology and the dynamics of the host receptor – virus ligand interaction.
- Identification of receptor and ligand (sub)units that could be targeted by preventive or therapeutic intervention. [Read More](#)

HEALTHY AND ENVIRONMENTALLY-FRIENDLY FOOD

4	New detection methods on products derived from new genomic techniques for traceability, transparency and innovation in the food system	HORIZON-CL6-2023-FARM2FORK-01-11	RIA	22 Dec 2022	12 Apr 2023
<p>Proposals are expected to contribute to the development and validation of detection methods of products obtained through new genomic techniques, including all of the following activities:</p> <ul style="list-style-type: none"> • Examine innovative ways and/or specific markers that would allow for distinction between products resulting from new genomic techniques subject to the GMO legislation and products that are not subject to the GMO legislation. This should not only entail the detection of specific mutations, but also of other markers in the genome that are specific for the genotype containing the mutation/s. The methods should be able to distinguish between identical mutations obtained through different techniques; • Development and validation of reliable detection methods including when possible quantification. Such methods could focus on products with known mutations (i.e. DNA sequence known) or on products with unknown mutations; • The proposed detection methods should focus on a wide applicability of all or a subgroup of products, allowing for a screening approach. These methods should be assessed on pure products as well as on mixtures typical of food or feed products in the market. Proposals should always include plant-based products and may include also animal and/or microorganisms-based products. • The proposal could also focus on the detection of unintended mutations or insertions (foreign DNA, CRISPR-Cas sequences, etc); • The proposals could also include digital/virtual/AI modelling aspects along with the detection methods alternatives; • The development and validation of standardized methodologies and the contribution to future standardisation processes is encouraged. Read More 					

BIOFUELS

5.	Development of smart concepts of integrated energy driven bio-refineries for co-production of advanced biofuels, bio-chemicals and biomaterials	HORIZON-CL5-2024-D3-02-03	RIA	17 September 2024	04 February 2025
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Proposals should address several of the following areas:

- Development of zero-waste and neutral or negative carbon emission energy-efficient biorefinery concepts for enabling the production of low-cost advanced biofuels through co-production of added value bio-based products and bioenergy.
- Conversion of biogenic wastes and residues as well as algae and aquatic biomass through chemical, biochemical, electrochemical, biological, thermochemical pathways or combinations of them in highly circular processes are in scope.
- Technology validated in relevant environment is required. International cooperation with **Mission Innovation countries is expected**.
- Proposals should provide information and assessment about the economic feasibility and the potential of scaling-up the technology at commercial scale as appropriate. [Read More](#)

NOTE: DBT will support projects for development and demonstration of zero waste integrated biorefinery with focus on agriculture wastes/residues as well as algae and aquatic biomass.

To note that the type of collaborative actions, Research and Innovation (RIA) and Innovation Actions (IA) are established by Horizon Europe, and to be understood as follows:

- **Research & innovation action (RIA)** that establishes new knowledge or explores a new or improved technology, product, process, service or solution.
- **Innovation action (IA)** that produces plans or designs for new or improved products, processes or services including prototyping, testing, demonstrating, piloting, large-scale product validation and market replication.

Technology Readiness Levels

Where the specific call conditions require a Technology Readiness Level (TRL), the following definitions apply, unless otherwise specified:

- TRL 1 — Basic principles observed
- TRL 2 — Technology concept formulated
- TRL 3 — Experimental proof of concept
- TRL 4 — Technology validated in a lab
- TRL 5 — Technology validated in a relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 6 — Technology demonstrated in a relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 7 — System prototype demonstration in an operational environment
- TRL 8 — System complete and qualified
- TRL 9 — Actual system proven in an operational environment (competitive manufacturing in the case of key enabling technologies, or in space)

SECTION 2: MODALITIES OF PARTICIPATION & FUNDING FOR INDIAN APPLICANTS

1. PARTICIPATION

1.1. Participation of Indian

Participation entity in Horizon Europe projects

- Eligibility of Indian entities is defined by DBT.

- Since the Indian entity is not receiving funding from the EU under Horizon Europe, it is not required to sign the EU Grant Agreement. It will participate as “**Associated Partner**” and mentioned as such in Article 9.1 of the EC grant Agreement.
- This means that the Indian entity is expected to contribute to the smooth implementation of the project as specified in the consortium agreement.

Formality for Participation

- If you want to participate in a Horizon Europe project proposal, your organisation needs to be registered in the Participant Register of the Funding & Tenders Portal and have a 9-digit [Participant Identification Code \(PIC\)](#) number (see registration procedure in Annex 2)

Number of Indian entities per projects

- There is no legal requirement on number of Indian entities in a given project eligibility condition. Any legal entity/organization (public or private research institute/university) established in India with expertise in relevant and distinct disciplines. No limit on number of Indian participants but each partner should be necessary for the execution of the project and comply with the eligibility conditions. The scientific R&D performing Indian industry may participate voluntarily in this call with participating Indian industry investing its own resources or come in collaboration with research/academic organization, but by investing their own resources (see section 2).
- The call is open to all career groups (i.e. early, intermediate and senior); however, it is expected that each investigator shall have adequate service tenure to accommodate key research, coordination, outreach, post completion handholding and maintenance (if any) responsibilities. Early career investigators are encouraged to participate.
- Each participating legal entity/organisation (public or private research institute/university) should be represented by at least two investigators.
- The number of Indian project partners should be optimum and correspond to the objectives of the project. The proposal should clearly demonstrate each partner’s essentiality, complementarities, and added- value in jointly addressing the topic.
- In case there is more than one Indian legal entity/organization participating in a given project, it is advised that the Indian participants appoint among them a ‘Lead Scientific Coordinator-INDIA’, who can represent the Indian participants in the consortium vis-à-vis DBT. To ensure continuity in the project, at least two investigators must represent each participating legal entity/organization.

1. 2. Participation of European

Number of European entities per projects

- Collaborative research & innovation projects carried out by consortia of organisations working together on specific research & innovation areas. A consortium must include at **least 3 partner organisations from 3 different Member States or associated countries**. At least **one of the 3 partners must be from Member States**.
- **European Union member states (EU27):** *Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden.*

- **Countries Associated with Horizon Europe:** *Agreements in place: Albania, Armenia, Bosnia and Herzegovina, Faroe Islands, Georgia, Iceland, Israel, Kosovo, Moldova, Montenegro, North Macedonia, Norway, Serbia, Tunisia, Turkey and Ukraine.*
- The EU is still in the process of association negotiations with Morocco, New-Zealand and United Kingdom's (UK) - *See updates updated¹ - HE association agreements status as of 15.01.2023*
- In addition to these three partners, any legal entity from anywhere in the world can be included in the consortium. Please consult the Horizon Europe programme guide².

1.3. Gender Balance

Applicants are encouraged to promote equal opportunities in the implementation of the action by ensuring a balanced participation of women and men at all levels of the research and innovation teams and in the management structures.

2. ELIGIBILITY

The participating entities/organisations from India have to be a legal entity as per Indian law (Indian applicants) and the European entities as per the [Horizon Europe rules of participation](#).

2.1. Indian Entities Eligible to Participate

- Government of India **supported or recognised Public or Private academia and research organisations** (research institutes & universities);

Indian entities

Academic/Research Partners:

- *Public and/or private universities and research organisations must have a well-established research support system, for basic or applied research; and*
- *Submission of proof of establishment under Indian statute; recognition documents and registration at Government of India's Public Finance Management System (PFMS) - <https://pfms.nic.in> shall be obligatory.*

Ineligible organisations:

- *Research centres and academic organisations headquartered and owned outside India and their subsidiaries in India, or vice versa, are not eligible to receive funding from DBT under this programme.*

2.2. European Entities Eligible to Participate

- Any legal entity is eligible to participate, provided that the conditions laid down in the Horizon Europe Regulation have been met, along with any other conditions laid down in the specific call topic³.

¹ • https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/list-3rd-country-participation_horizon-euratom_en.pdf

3. FUNDING

3.1 Funding by DBT

DBT will fund the Indian partners/entities in a successful project, as per requirement of the project, for the project duration up to 3-4 years.

Budget should be commensurate with the essentiality of participation, workload, objectives of the project and cost of participation.

3.1.1 Eligibility for Funding

Budgeted costs of the project to legal entities subject to obligatory fulfilment of eligibility criteria:

- DBT will support (Grant-in-aid) 100% of the approved budget costs to Government of India supported or recognised public or private academic institutions or research organisations;
- Eligible costs for funding are: Capital expenditure (equipment's) || Manpower || Consumables || Travel (local and international* travel) || Contingency || Overheads || Outsourcing || others. (*Academia can factor in additional sub heads (in other category) such as training & awareness; workshops; publications; review meetings, etc. under expenditure based on the requirement of the project.*)
* The travel of investigator(s) and project staff (s) will be as per prevailing Government of India guidelines.

3.1.2 Non-Admissible Cost from DBT

- i. Prosecution/litigation costs;
- ii. Salary of investigators;
- iii. Capital expenditure for the purchase of assets such as office furniture, motor vehicles, Office equipment viz. desktops, laptops, tablets, cell phones, scanners, printers, photocopy machines, and renovation or extension of facilities such as buildings and laboratories;
- iv. Capital expenditure toward technology(ies), demonstration plants and associated field equipment(s), hardware, software etc. for test and analysis from consortium partner(s) from abroad;
- v. Expenditure toward rental and utilities;
- vi. International travel to countries other than the one participating within the consortia in a particular call topic of Horizon Europe;
- vii. Mere attendance at conferences/ symposiums/ congresses

3.2 Funding by EU

Funding of European partners is as per Horizon Europe rules of participation and in function of type of action [RIA & IA]⁴.

³ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2021-2022/wp-13-general-annexes_horizon-2021-2022_en.pdf (page 5)

⁴ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/programme-guide_horizon_en.pdf

3.3 IPR: Ownership, Protection & User rights

- IPR legislation and other rules are often crucial for participants in research projects, as they may have a deep influence on the way in which the knowledge can be shared during a project development, and in which project results can be commercially used.
- The participants shall jointly develop a Consortium Agreement (CA). The CA is a specific agreement to be concluded between the participants in joint research, defining, among other things, ownership, protection, user rights for research and development purposes, exploitation and dissemination, including arrangements for joint publication, the rights and obligations of visiting researchers and dispute settlement procedures. The CA shall also address foreground and background information, licensing and deliverables.
- The IPR issues for all the proposals need to satisfy the S&T agreement between EU and India

4. PREPARATION OF PROPOSAL

The Indian and European participants must formulate a joint proposal, according to the requirements and [templates](#) provided by respectively Horizon Europe Funding & Tenders Portal format⁵ and DBT's administrative and financial requirements (see annex 1). Complying with the formats and templates of Horizon Europe and DBT for the Indian partners is mandatory. Indian entities should participate as an **Associated Partners**.

The Horizon Europe proposal consists of two main parts:

- **Part A:** the **Administrative Forms** containing general information on the project (title, abstract, and keywords), the consortium (basic administrative data, contact persons, declarations) and the budget overview.
- **Part B:** the **Technical Annex** containing the detailed description of the planned research and innovation project. The structure is based on the evaluation criteria (cite them here) as provided in the proposal template for a RIA/IA.

How to Add Associated Partners to a Proposal on the Funding & Tenders Portal

Entities based in India can participate to Horizon Europe projects by applying under the participant role of “**Associated Partners**” (AP).

This is a step-by-step guide on (to be done via European proposal coordinator):

- how to add an AP to a proposal on the Portal
- how to include the budget of an AP on the Portal
- how to deal with the budget table for Lump Sum projects

⁵ https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/temp-form/af/af_he-ria-ia_en.pdf

Associated Partner

2 **IND organisation (name)**

IND organisation (full name)
Address
PIC number

Change organisation **Contact organisation**

APs CAN NOT ADD their contacts details. This means: no access to the Portal for the AP

Possible solution as work-around
— The Coordinator might add the AP contact among its Coordinator's contacts

How to Add an AP to the proposal

Coordinator

1 **Institution (name)** **Add Affiliated Entity +** **Contacts: 0** **Add contact +**

Institution (full name)
Address
PIC number

Contact (name) **Main contact**

Change organisation **Contact organisation**

Add Partner + **Add Associated partner +**

How to Include the Budget of an AP

No	Participant name	Country	Estimated expenditure					Estimated income					Total estimate of income (j)=(k)+(l)+(m)+(n)+(o)+(p)			
			Estimated eligible costs					Requested EU contribution			Revenues	Other sources of financing				
			EU contribution to eligible costs					Funding rate (l)	Maximum EU contribution to eligible costs (k) = (j) * (l)	Requested EU contribution to eligible costs (m) (n)	Income generated by the action (o)	Financial contributions (p)		Own resources (q)		
			A. Personnel costs/€ (a1)	B. Subcontracting costs/€ (b)	C. Purchase costs		D. Other cost categories (d)(x)								E. Indirect costs/€ (e) = 25% * ((a1) + (b) + (c1) + (c2) + (c3) + (d))	Total eligible costs (j) = (a1) + (b) + (c1) + (c2) + (c3) + (d) + (e)
C.1 Travel and subsistence/€ (c1)		C.2 Equipment/€ (c2)	C.3 Other goods, works and services/€ (c3)		D.X (specific cost categories) (dx)											
1	Participant 1	NL														
2	Participant 2	LB														
	Affiliated Entity	LB														
3	Participant 3	DE														
	Associated Partner	AR														
Total																

“Financial Contribution”. Insert here the total amount that the Indian entity participating as an AP intends to request to DBT.

In general, this budget category is used for any financial contribution expected to be received/ already received from other sources for being used specifically for the same action as the one submitted for funding under Horizon Europe (e.g. funding from DBT).

Tasks attributed to the Associated Partner must be described in the technical description (Part B) of the project. If you wish, you can also include in this section the estimated budget of the entity (not mandatory).

Indian participants prepare budget (in Rupees) according to DBT requirements and templates

- Indian participants **MUST** submit detailed financial plan in **Indian Rupees (₹)** for duration of the project to DBT only.
- The detailed Indian financial plan for each Indian participant in the project must be specified according to format provided by DBT in [Annex 1](#): Indian academic partners must use "Budget Format - Academic Partner" (*at para 7.2*).

DBT's budget calculation for Indian participants

Indian participant must ensure that each Indian participant follows budget format proposed by the DBT.

Direct Costs:

- 1) **Manpower cost:** as per the requirements of the project (emoluments will be as per prevailing Gov. of India norms);
- 2) **Mobility of investigator(s) & project staff(s):** for visit(s) and work related to the project to be undertaken by Indian investigator(s) & project staff(s) **in Europe**, the cost of travel and man-days of stay in European countries (i.e. round-trip international travel by economy class, admissible insurances, local transport, boarding and lodging) must be justifiably budgeted by respective Indian organisation for each year, at 7.1 and 7.2 (as applicable) of [Annex 1](#). The travel of investigator(s) and project staff (s) will be as per prevailing Government of India guidelines.
Institution hosting the collaborating investigator(s) & project staff(s) of other consortium participants, shall provide research facility and research resources to accomplish defined objectives and if required, this can be reflected in each participant budget adequately.
- 3) **Overhead/Indirect Cost:** overhead expenses payable to legal entity/organization for Indian partners, up to 10% of the total project cost for educational institutions and up to 8% for laboratories and institutions under central Government Departments/Agencies as per prevailing Gov. of India norms.

//to be noted //

- *Indian entity(ies) will submit detailed financial plan in Indian Rupees only to DBT*
- *The budget that DBT provides to Indian participants does not cover expenses incurred by the European and other countries' applicants in the consortium.*
- *Indian entity(ies) will not sign EC's Grant Agreement but considered as 'Associated Partners'.*

SECTION 3: REGULATORY & ETHICAL CONSIDERATIONS (IF APPLICABLE)

1. Notifications/ Orders issued towards expeditious consideration of various regulatory aspects in response to COVID-19 pandemic

- Rapid Response Regulatory Framework for COVID-19 to deal with applications for development of Vaccines, Diagnostics, Prophylactics and therapeutics
→ http://dbtindia.gov.in/sites/default/files/uploadfiles/om_covid19%20April%202020.pdf
- Interim Guidelines on Laboratory Biosafety to Handle COVID-19 Specimen for R&D Purpose
→ https://ibkp.dbtindia.gov.in/Content/FlashPDF/OM_Interim_Guidance_COVID.pdf
- Rapid Response Regulatory Framework for COVID-19 Vaccine Development
→ https://ibkp.dbtindia.gov.in/Content/FlashPDF/Checklist_Recombinant%20Vaccine%20COVID%2019.pdf
- Guidelines for sharing of Bio-specimen and Data for Research related to COVID-19
→ <https://niti.gov.in/sites/default/files/2020-04/Guidelines-for-sharing-of-Biospecimen-and-data-for-research-related-toCOVID-19..pdf>
- SOP Template for Ethics Review of Biomedical and Health Research During Covid-19 Pandemic, 2020
→ http://ethics.ncdirindia.org//asset/pdf/SOP_Template_EC_COVID19.pdf
- National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, 2020
→ http://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf

2. Research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof for R&D purpose

In India, research using hazardous microorganisms, genetically engineered (GE) organisms & products thereof are governed under Rules, 1989 (Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/ Genetically Engineered Organisms or Cells) of Environment (Protection) Act, 1986, according to which, necessary intimation/ recommendation/ authorization from concerned Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) & Genetic Engineering Appraisal Committee (GEAC) is obligatory based on type & scale of research operations.

Further guidance on regulatory considerations can be obtained from:

- Guidelines and Handbook for IBSCs, 2011
http://dbtindia.gov.in/sites/default/files/uploadfiles/Guidelines%20Handbook_2011.pdf
- Regulations and Guidelines on Biosafety of Recombinant DNA Research & Biocontainment, 2017
<http://www.dbtindia.nic.in/wp-content/uploads/Draft-Biosafety-Regulations-and-Biocontainment-Guidelines-2017-FF.pdf>
- Recommendations for Streamlining the Current Regulatory Framework, 2005
http://www.moef.nic.in/divisions/csurv/geac/draftreport_rpharma.pdf

3. Human and Animal Subjects Research

DBT and the European Commission are committed to ensure that projects involving human or animal subjects are protected from research risks in compliance with the rules and policies in respectively the EU and India (ICMR/DBT policies).

All projects recommended for award that involve human or animal subjects will undergo Horizon Europe ethics review⁶ as well as a review by the Indian Bioethics Committees prior to award request.

For information on ICMR policies, please consult:

- Handbook on National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2018
http://ethics.ncdirindia.org//asset/pdf/Handbook_on_ICMR_Ethical_Guidelines.pdf

India PIs of the consortium should apply to their institutional review boards (IRBs)/ institutional ethics committees (IECs) **at the time of submission of proposal** to obtain necessary bioethics approvals from all involved institutions.

4. Authorizations for pre-clinical and/or human clinical trials

While exploring vaccine developmental studies in India, Investigators must satisfy regulatory and ethical provisions adopted under:

- Drugs and Cosmetics Rules, 1945 (as amended from time to time) of Drugs and Cosmetics Act, 1940
- Committee for the purpose of Control and Supervision of Experiments on Animals.
<http://cpseia.nic.in/Auth/index.aspx>
- Schedule 'Y' of Drugs and Cosmetics Rules, 1945 || Requirements and Guidelines for Permission to Import and/or Manufacture of New Drugs for Sale or to undertake Clinical Trials: http://cdsco.nic.in/html/D&C_Rules_Schedule_Y.pdf
- Guidance for Industry on Preparation of Common Technical Document for Import/Manufacture and Marketing Approval of New Drugs for Human Use (New Drug Application-NDA):
<http://www.cdsco.nic.in/writereaddata/CDSCO-GuidanceForIndustry.pdf>
- Handbook: Good Laboratory Practice (GLP). Quality practices for regulated non-clinical research and development, 2nd ed. Geneva, World Health Organization, 2009 ||
<http://www.who.int/tdr/publications/documents/glp-handbook.pdf>
- Clinical Trials Registry of India (CTRI) – India
<http://ctri.nic.in/Clinicaltrials/login.php>

SECTION 4: PROCESS FOR SUBMISSION OF PROJECT PROPOSAL

All proposals with Indian applicants should be submitted to both Horizon Europe Funder & Tenders portal and to DBT.

⁶<https://webgate.ec.europa.eu/funding-tenders-opportunities/display/OM/Special+procedures%3A+Ethics+review%2C+security+scrutiny%2C+Ownership+control+check>

1. Submission of proposal on Horizon Europe Funding & Tenders Portal

A joint proposals must be submitted electronically using the electronic submission system of the Funding & Tenders Portal⁷. This task will be done by designated European Project Coordinator. Please ensure he/she gets all the required information from Indian participant(s) on time. In preparation thereof, Indian applicants should have their Personal Identification Code (PIC). See Annex 2 hereunder. For more information, see [Proposal Submission Service User Manual](#)⁸.

2. Submission to DBT of the proposal including budget requested from DBT

The Indian participant(s) must submit the **complete proposal**, (Part A + Part B) and **same** as submitted on the Horizon Europe Funding & Tenders Portal), as one single consolidated PDF file + DBT's administrative and financial form to DBT **within 7 working days of closer of call deadline**.

(A)	Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential	HORIZON-HLTH-2023-DISEASE-03-04	icone@dbt.nic.in
	Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders	HORIZON-HLTH-2024-DISEASE-03-13-two-stage	
	Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential	HORIZON-HLTH-2024-DISEASE-08-20	
	New detection methods on products derived from new genomic techniques for traceability, transparency and innovation in the food system	HORIZON-CL6-2023-FARM2FORK-01-11	
(B)	Development of smart concepts of integrated energy driven bio-refineries for co-production of advanced biofuels, bio-chemicals and biomaterials	HORIZON-CL5-2024-D3-02-03	balendra.singh@dbt.nic.in

Please note that the proposal will be disqualified if not submitted to DBT to above indicated email ID by indicated date. Absence of timely submission or any discrepancy found in the proposal submitted at Horizon Europe Funding & Tenders Portal and to DBT will result in disqualification from consideration by DBT for funding.

After completion of HE peer review process, Indian participant(s) in shortlisted HE proposals will be requested to submit:

- A duly signed (*by the Lead Coordinator-INDIA*) and transmitted (*by the Utmost Authority of the organization*) short covering letter introducing the application, along with complete proposal to the concerned DBT contact point.

⁷ <https://webgate.ec.europa.eu/funding-tenders-opportunities/pages/viewpage.action?pageId=1867927>

⁸ https://ec.europa.eu/research/participants/data/support/sep_usermanual.pdf

- A comprehensive facts about administrative, statutory, ethical and financial considerations (including diligent justification for proposed budgetary requirements) in the form of checklist

3. Submission to Horizon Europe Funding & Tenders Portal

- In order to submit a proposal, any applicant (from Europe or India) needs to be registered by the European Commission and obtain for this purpose a Personal Identification Code also called PIC: see registration procedure in [Annex 2](#)).
- Online guidance is also provided on how to fill in the administrative forms (Part A).
- Proposal templates for the technical annex can be downloaded from the system. The technical annex and any additional annexes have to be uploaded as PDF documents.
- The Templates to comply with for DBT requirement are available on DBTs website only.

For more details see: <https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/how-to-participate/how-to-participate/1>

FURTHER INFORMATION

DBT contacts:

(A)	Pandemic preparedness and response: Broad spectrum anti-viral therapeutics for infectious diseases with epidemic potential	HORIZON-HLTH-2023-DISEASE-03-04	Dr. Abhishek Singh, Scientist 'D', DBT icone@dbt.nic.in
	Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders	HORIZON-HLTH-2024-DISEASE-03-13-two-stage	
	Pandemic preparedness and response: Host-pathogen interactions of infectious diseases with epidemic potential	HORIZON-HLTH-2024-DISEASE-08-20	
	New detection methods on products derived from new genomic techniques for traceability, transparency and innovation in the food system	HORIZON-CL6-2023-FARM2FORK-01-11	
(B)	Development of smart concepts of integrated energy driven bio-refineries for co-production of advanced biofuels, bio-chemicals and biomaterials	HORIZON-CL5-2024-D3-02-03	Dr. Balendra Singh, Scientist 'D', DBT balendra.singh@dbt.nic.in

EU Contacts:

- DELEGATION-INDIA-RI@eeas.europa.eu

ANNEX 1: TEMPLATES FOR ADMINISTRATIVE & FINANCIAL CONSIDERATIONS

As this is a fast track procedure, DBT requests Indian Investigator or in the case of more Indian partners in one proposal, the Lead Coordinator-INDIA, to provide information proforma allowing DBT to speed up the granting time, in the interest of quickly starting the research work, as required by the special call for Expressions of Interest.

General Instructions:

- *Make sure that all investigators shall thoroughly understand the call text and requirements of participation & funding, before attempting to fill this proforma*
- *All fields are mandatory. Therefore, all sections of this proforma must be completed. If the space provided is not sufficient, attach additional supporting materials as necessary. Page numbering and headings of any supplementary material must match corresponding sections in filled-in proforma.*
- *Kindly read the footnotes and furnish information/ data, accordingly.*
- *Each field demands distinct attention, and diligent answer. Therefore, avoid mere replication of information*
- *Project shall not be pursued if it is incomplete or any of the requirements mentioned herein missing*
- *To accomplish official considerations, successful proposal(s) shall be asked to submit comprehensive facts about administrative, statutory, ethical and financial considerations (including diligent justification for proposed budgetary requirements).*

<u>SR. NO.</u>	<u>PARTICULARS</u>												
1.0	GENERAL INFORMATION												
1.1	Duration of the Project [<i>in months</i>]												
1.2	Proposed cost of the project [<i>Cumulative (non-recurring & recurring), as well as Segregated project cost proposed for Indian and EU participants In INR</i>]												
1.3	Objectives of the proposal [<i>only one-two liner, must be interdependent, and to be submitted as bullet points NMT 100 words</i>]												
2.0	<p>Status of EACH of the INDIAN participating legal entity/organization and, fulfilling various registration requirements, as explained in participation modalities.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2" style="text-align: center;">Name of the participating Organization →</th> <th style="text-align: center;">Organization 1</th> <th style="text-align: center;">Organization 2...</th> </tr> </thead> <tbody> <tr> <td style="width: 30%; vertical-align: top;"> <p>[<i>Select the one, whichever is applicable</i>]</p> </td> <td style="vertical-align: top;"> <p>Public or private university and/or research organization</p> <p style="text-align: center;">[OR]</p> <p>Private R&D performing institution; Not-for-profit, NGO/ VO/ Trust/ Research foundation</p> </td> <td></td> <td></td> </tr> <tr> <td style="vertical-align: top;"> <p>[<i>Pl. mark "X" for whichever is AVAILABLE</i>]</p> </td> <td style="vertical-align: top;"> <p>Proof of establishment under Indian statue</p> <p>Proof of registration at Gol Public Finance Management System (PFMS)</p> <p>Proof of registration at 'NGO DARPAN' of NITI Aayog</p> <p>Certificate of registration under Society Registration Act</p> <p>VALID SIRO certificate for in-house R&D recognition</p> </td> <td></td> <td></td> </tr> </tbody> </table>	Name of the participating Organization →		Organization 1	Organization 2...	<p>[<i>Select the one, whichever is applicable</i>]</p>	<p>Public or private university and/or research organization</p> <p style="text-align: center;">[OR]</p> <p>Private R&D performing institution; Not-for-profit, NGO/ VO/ Trust/ Research foundation</p>			<p>[<i>Pl. mark "X" for whichever is AVAILABLE</i>]</p>	<p>Proof of establishment under Indian statue</p> <p>Proof of registration at Gol Public Finance Management System (PFMS)</p> <p>Proof of registration at 'NGO DARPAN' of NITI Aayog</p> <p>Certificate of registration under Society Registration Act</p> <p>VALID SIRO certificate for in-house R&D recognition</p>		
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		<table border="1"> <tr> <td>Audited account statements for the past three years</td> <td></td> <td></td> </tr> <tr> <td>Certificate of Incorporation issued under Companies Act</td> <td></td> <td></td> </tr> <tr> <td>Firm's Memorandum of Association</td> <td></td> <td></td> </tr> </table>	Audited account statements for the past three years			Certificate of Incorporation issued under Companies Act			Firm's Memorandum of Association								
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Certificate of Incorporation issued under Companies Act																	
Firm's Memorandum of Association																	
3.0	<p>Whether EACH of the INDIAN Project Investigator has valid service tenure to accommodate key research and other responsibilities assigned by the consortium? [-- YES/NO --]</p> <p>- If yes, provide valid answer for the same with date of superannuation [NMT 30 words]</p> <p>- If no, Provide details of precautionary approach to be followed in case of exigency [NMT 80 words]</p>																
4.0	WORK DIVISION																
4.1	<p>Provide explicit ROLE(s) assigned to EACH participating investigator (<i>Indian & EU counterparts</i>) to be involved in this project.</p> <table border="1"> <thead> <tr> <th>Sr. NO.</th> <th>NAME OF THE INVESTIGATOR</th> <th>PARTICIPATING IN THE CONSORTIUM AS <i>(Project Coordinator/ Lead Coordinator-INDIA/CO-PI/CO-I)</i></th> <th>ORGANIZATION'S ABBREVIATED NAME</th> <th>ROLE(S) ASSIGNED</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>2...</td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	Sr. NO.	NAME OF THE INVESTIGATOR	PARTICIPATING IN THE CONSORTIUM AS <i>(Project Coordinator/ Lead Coordinator-INDIA/CO-PI/CO-I)</i>	ORGANIZATION'S ABBREVIATED NAME	ROLE(S) ASSIGNED	1					2...					
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1																	
2...																	
4.2	<p>Provide explicit RESPONSIBILITY(ies) assigned to EACH participating investigator (<i>Indian & EU counterparts</i>) to be involved in this project.</p> <table border="1"> <thead> <tr> <th>Sr. NO.</th> <th>NAME OF THE INVESTIGATOR</th> <th>RESPONSIBILITIES ASSIGNED</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td></td> </tr> <tr> <td>2...</td> <td></td> <td></td> </tr> </tbody> </table>	Sr. NO.	NAME OF THE INVESTIGATOR	RESPONSIBILITIES ASSIGNED	1			2...									
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2...																	
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1																	
2...																	
5.0	IMPORTANCE, EXPECTATION & OUTCOME																
5.1	How the project relates to India specific and global aspiration?																
5.2	Describe briefly the importance of proposed research & innovation for the scientific community, and the impact you expect from the project on research, training and teaching in your field/discipline in short and/or long term																
5.3	<p>Provide explicitly the anticipated provisions toward ensuring country's preparedness in mitigating various health emergencies such as "COVID-19" caused by SARS-CoV-2.</p> <p><i>[Please note that while seeking this clarity our expectations are way beyond training of human resource or establishing laboratory infrastructure]</i></p>																
5.4	Explain what differentiates your project's likely outcome, and provides the highest added value (<i>in quantitative and qualitative terms</i>) for INDIAN industries, SMEs, policy makers, society, etc. in short and/or long term																

		<i>[In a two page note you should make it clear where your project is positioned in the value chain and state which & how the realistic value will be created overtime]</i>				
6.0		DESCRIBE THE FOLLOWING				
		<i>[Kindly note that the IPR issues need to be in compliance with the S&T agreement between EU and India]</i>				
6.1		Provide details of each of the IPs (patent, copyright, trademarks etc.) within the consortium (<i>including of outsourcing partners</i>) already “PROTECTED” , so far; and commercial ownership of the same (as applicable) which would likely to impact the project under consideration				
6.2		Provide details of each of the knowhow, models, algorithms, technology(ies) and technology interventions ‘within the consortium (<i>including of outsourcing partners</i>)’ already “GENERATED” , so far; which would likely to impact the project under consideration				
6.3		Summary of your freedom to operate above mentioned knowhow(s) and/or IPs during the tenure and beyond the tenure of the project				
7.0		BUDGETARY REQUIREMENTS				
7.1		Details of Consolidated budget proposed				
		(Rs. In lakhs)				
		Heads	Year I	Year II	Year III...	Total
		Equipment(s)				
		Manpower				
		Consumables				
		Travel				
		a. Domestic				
		b. International *				
		i. Expenditure for travel of investigator(s) to EU				
		ii. Expenditure for travel of project staff(s) (preferably registered PhDs and/or Postdocs) to EU				
		iii. Expenditure for stay of investigator(s) in EU				
		iv. Expenditure for stay of project staff(s) (preferably registered PhDs and/or Postdocs) in EU				
		c. Subsistence cost for visiting Indian counterpart investigator(s) and/or project staff(s) within India				
		Contingency				
		Overheads				
		Outsourcing				
		Other (Provide details).....				
		Total				
		<i>*The travel of investigator(s) and project staff (s) will be as per prevailing Government of India guidelines</i>				
		<i>(N.B: Academia can factor in additional sub heads (in other category) such as training & awareness, review meeting, consultancy charges, field & farm expenses, etc. based on the requirement of the project.)</i>				
7.2		Details of Investigator-wise and/or organization wise & year wise final budget proposed: <i>[Critically review the budget requirements, ensuring every possibility of using existing resources & communication technologies or possibly sharing the same from alternative sources (outsourced) without impacting time and efforts to achieve the goal]</i>				
		(Rs. In lakhs)				
		Heads	Year I	Year II	Year III...	Total
		Equipment(s)				
		Manpower				

	Consumables				
	Travel				
	a. Domestic				
	b. International*				
	i. Expenditure for travel of investigator(s) to EU				
	ii. Expenditure for travel of project staff(s) (preferably registered PhDs and/or Postdocs) to EU				
	iii. Expenditure for stay of investigator(s) in EU				
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	Outsourcing				
	Other (Provide details).....				
	Total				
	*The travel of investigator(s) and project staff (s) will be as per prevailing Government of India guidelines				
	(N.B: Academia can factor in additional sub heads (in other category) such as training & awareness, review meeting, consultancy charges, field & farm expenses, etc. based on the requirement of the project)				
8.0	UNDERTAKING & ENDORSEMENTS				
8.1	<p>a) The research work proposed in the scheme/project entitled "....." does not in any way duplicate the work already done or being carried out elsewhere on the subject.</p> <p>b) Certified that above information is true to the best of our knowledge</p> <p>[Name, Signature and Stamp of Lead Coordinator-INDIA (On behalf of all participating investigators)]</p> <p><i>Forwarded by</i> [Name, Signature & Stamp of Executive Head of Institution/ Organization/ University]</p>				
8.2	Enclose a letter of collaboration and submission of joint proposal (<i>with the project title</i>) from <u>Project Coordinator</u>				
8.3	<p>Endorsement by the Head of the legal entity/organization: (<i>to be submitted on letter head in support of <u>individual participating investigator</u> of the concerned organization as per the proforma placed below</i>)</p> <p style="text-align: center;"><u>Endorsement by the Head of the Organization</u> <i>To be submitted on letter head in support of individual participating investigator</i></p> <p>Project Title:</p> <p>I. Certified that the institution welcomes participation of Dr. _____ as the Principal Investigator and Dr. _____ as the Co-Principal Investigator (Co-PI) or Co-Investigator (Co-I) for the project and, in the unforeseen event of discontinuance by the Principal Investigator, the Co-PI or Co-I will assume the responsibility of the fruitful completion of the project [with due information to the Department of Biotechnology (DBT)].</p>				

II. Certified that all resources (infrastructure, techno-scientific, administrative, etc.) as per the terms and conditions of the grant, will be extended to investigator(s) throughout the duration of the project.

III. Organization assumes to undertake the financial and other management responsibilities of the project.

IV. Certified that comprehensive appraisal pertaining to administrative, financial, ethical, regulatory & statutory requirements has been made towards participation of this organization through this project, beforehand.

V. We thoroughly understood the modalities of participation & funding, and shall abide to it.

VI. We hereby commit to obtain all applicable (central & state) environmental, regulatory & statutory as well as local governmental authorizations, prior to the commencement of relevant research, innovation & translation activities.

VII. We agree to accept the terms and conditions of Department of Biotechnology, Govt. Of India.

VIII. The details & information given in the project proposal are true & factual.

Date:

**Name & Signature with Stamp
of Head of the Organization**

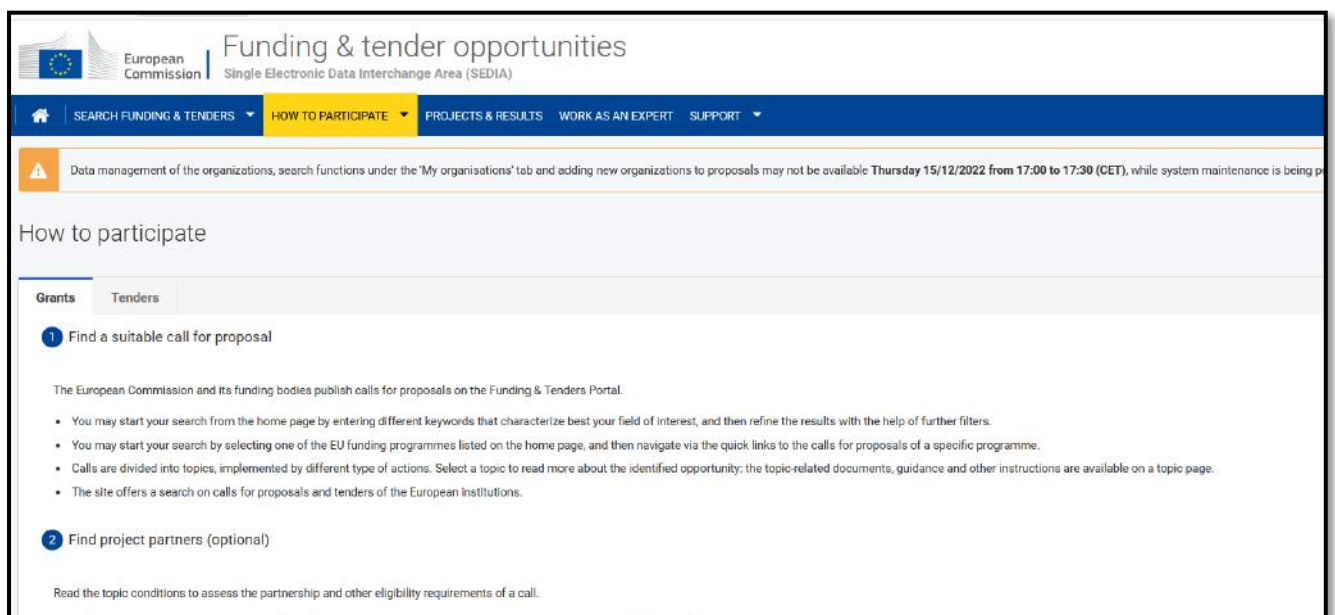
Place:

ANNEX 2: HOW TO ACCESS HORIZON EUROPE PORTAL & FORMALITIES

How to Participate:

By selecting the “[How to Participate](#)” tab on the Horizon Europe Funding & Tenders Portal “Home” page, researchers and innovators will be directed to a page that provides easy access and instructions for using key parts of the portal (see screen shot below):

- Create an Account
- Register an Organization
- Find Partners
- Find a Call for Proposals
- Submit a Proposal



The screenshot shows the 'How to participate' page on the Horizon Europe Funding & Tenders Portal. The page header includes the European Commission logo and the text 'Funding & tender opportunities Single Electronic Data Interchange Area (SEDIA)'. The navigation menu is highlighted, with 'HOW TO PARTICIPATE' selected. A warning message is displayed: 'Data management of the organizations, search functions under the 'My organisations' tab and adding new organizations to proposals may not be available Thursday 15/12/2022 from 17:00 to 17:30 (CET), while system maintenance is being performed.' The main content area is titled 'How to participate' and has two tabs: 'Grants' and 'Tenders'. Under the 'Grants' tab, there are two numbered steps: 1. 'Find a suitable call for proposal' and 2. 'Find project partners (optional)'. Step 1 includes a paragraph: 'The European Commission and its funding bodies publish calls for proposals on the Funding & Tenders Portal.' followed by a bulleted list of search tips: 'You may start your search from the home page by entering different keywords that characterize best your field of interest, and then refine the results with the help of further filters.', 'You may start your search by selecting one of the EU funding programmes listed on the home page, and then navigate via the quick links to the calls for proposals of a specific programme.', 'Calls are divided into topics, implemented by different type of actions. Select a topic to read more about the identified opportunity: the topic-related documents, guidance and other instructions are available on a topic page.', and 'The site offers a search on calls for proposals and tenders of the European institutions.' Step 2 includes a paragraph: 'Read the topic conditions to assess the partnership and other eligibility requirements of a call.'

ANNEX 3: FINDING PARTNERS

The starting point is to consider partners with whom you already have direct or indirect connections. As participation in a Horizon Europe call requires an interdisciplinary and/or inter-sectoral approach for a challenge to be addressed appropriately, it may become necessary to look for partners outside the usual circle of contacts.

Hereunder you will find a list of European services that assist in finding the right partners:

Partner search tools	
Partner Search for organisation profiles on the EC platform	Find partners for your project ideas among the organisations registered in the Funding & Tenders Portal of the European Commission.
Find partners with the help of Enterprise Europe Network	The Enterprise Europe Network online database contains over 2,500 technology profiles (offers and requests) from companies and R&D organisations from over 60 countries in Europe and beyond.
Guide to an adequate partner search	Horizon Europe: Guide to an adequate partner search
Expressed Interest	Horizon Europe Funding & Tenders Portal: search by call topics where organisations have participated or expressed interest in participating in the future.
euMatch 2.0	Partner Search and Matchmaking platform to find partners and project initiatives to participate in H2020 supported health related projects.
NCP Network	National Contact Points for Horizon Europe